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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,014	02/17/2004	Markus Pompejus	BGI-126CPCN	2283

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/781,014	Applicant(s) POMPEJUS ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53, 57, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) 47-53, 57 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-46 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 39-53, 57, 59, 60 are pending in the instant application. Claims 47-53, 57, and 59 have been previously withdrawn from consideration as being drawn to a non-elected invention.
2. Claims 39-46 and 60 are under consideration in this Office Action.
3. The rejection of claims 39-46 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claims filed 06/20/2006.
4. The grounds of rejection of claim 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for transgenic plants and animals including humans transformed with the claimed vector has been withdrawn in view of applicants' amendment to the claim filed 06/20/2006.
5. The rejection of claim 39 is rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman et al. (US Patent 6,294,328) has been withdrawn in view of applicants' amendment to the claim filed 06/20/2006.
6. The rejection of claims 39, 41-44 and 46 under 35 U.S.C. 102(b) as being anticipated by Abrams et al. (US Patent 5,604,116) has been withdrawn in view of applicants amendment to the claims filed 06/20/2006.
7. Acknowledgment is made of applicant's claim for foreign priority based on 27 applications filed in Germany in 1999. It is noted, however, that applicant has not filed a certified copy of the 27 applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 39-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence that is 95% identical to SEQ ID NO: 179 and an isolated nucleic acid encoding the amino acid sequence SEQ ID NO: 180; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' arguments filed 06/20/2006 have been fully considered but are not persuasive for the reasons of record as supplemented below.

An undue amount of experimentation is required to make the isolated nucleic acid molecule which is at least 90% identical to SEQ ID NO: 179 or the complement thereof, where any 195 nucleotides in SEQ ID NO: 1 is changed using nucleotide substitution, insertion, deletion, addition, and combinations thereof, and then determining whether the polynucleotide can encode any functional phosphoenolpyruvate carboxykinase. Experimentation also entails searching and screening vast number of biological sources for any naturally occurring allelic variant of SEQ ID NO: 180 and then obtaining the nucleic acid encoding the variant. The specification does not provide guidance, prediction, and working examples for selecting these specific nucleotides to change. Thus, the above stated trial and error experimentation must be performed, which is considered undue experimentation.

Similarly, experimentation involves selecting any 25 contiguous nucleotides of SEQ ID NO: 179 and determining the biological function and use of the selected 25 contiguous nucleotides of SEQ ID NO: 179. General teaching regarding screening and searching for the claimed invention using phosphoenolpyruvate carboxykinase assays taught in the specification is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. Claims 40-46 which depend from claim 39 are also rejected because they do not correct the defect of claim 39.

Amending the claims to recite a nucleic acid molecule comprising a nucleotide sequence which is 95% identical to SEQ ID NO: 179 and encodes a polypeptide having phosphoenolpyruvate carboxykinase activity, and further amending claim 39 to recite an isolated fragment consisting of at least 25 contiguous nucleotides of SEQ ID NO: 179 may overcome the rejection.

10. Claims 39-46 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments filed 06/20/2006 have been fully considered but are not persuasive for the reasons of record as supplemented below.

Claim 39 is drawn to a genus of nucleic acid molecules comprising any fragment of at least 25 contiguous nucleotides of SEQ ID NO: 179. Claim 60 is drawn to a genus of nucleic acid molecules comprising a nucleotide sequence which is at least 95% identical to SEQ ID NO: 179. The scope of the each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists.

While the specification discloses a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 179 which encodes a phosphoenolpyruvate carboxykinase from *Corynebacterium glutamicum* consisting of the amino acid sequence of SEQ ID NO: 180; there is no recitation of any particular structure to function relationship in the claims which would define any biological properties and enzyme activities common to the members of each genus. Furthermore, the specification does not define any structure to function relationship for each claimed genus other than the polynucleotide of SEQ ID NO: 179 encoding a phosphoenolpyruvate carboxykinase consisting of the amino acid sequence of SEQ ID NO: 180. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of genus of nucleic acid molecules comprising any fragment of at least 25 contiguous nucleotides of SEQ ID NO: 179 and a genus of nucleic acid molecules comprising a nucleotide sequence which is at least 95% identical to SEQ ID NO: 179. Claims 40-46 which depend from claim 39 are also rejected because they do not correct the defect of claim 39.

Amending the claims to recite a nucleic acid molecule comprising a nucleotide sequence which is 95% identical to SEQ ID NO: 179 and encodes a polypeptide having phosphoenolpyruvate carboxykinase activity, and further amending claim 39 to recite an isolated fragment consisting of at least 25 contiguous nucleotides of SEQ ID NO: 179 may overcome the rejection.

Conclusion

11. No claim is allowed.


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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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